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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,611	07/30/2003	Koji Nozaki	030922	6117
38834	7590	05/19/2005	EXAMINER	
WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036			SANDERS, KRIELLION ANTIONETTE	
		ART UNIT	PAPER NUMBER	
		1714		

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/629,611	NOZAKI ET AL.
	Examiner Kriellion A. Sanders	Art Unit 1714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/10.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

## DETAILED ACTION

### *Specification*

1. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. An example of unclear, inexact or verbose terms used in the specification are the improper syntax at page 2, line 9.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In claim 2, lines 3 and 4 the claim should read ---- the biodegradable coating resin are selected from the group consisting of identical types of resins and different types of resins---.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1097967A2 in view of Frechtling et al, US Patent No. 3971753 and Olson et al, US Patent No. 6890546.

3. The European Patent discloses biodegradable resin compositions comprising a biodegradable polyester resin, such as polylactic acid and other known adjuvants including fillers, anionic surfactants, fibrous materials, flame retardants and nucleating agents. Patentee indicates one suitable filler material to be talc. Suitable nucleating agents include mica, talc, silica, phosphates and phosphates. These are all components set forth in applicant's claims and their properties are inherent to the components. The compositions of the invention may be formed into molded products. Patentee does not suggest the encapsulation of the filler in biodegradable resin, however he does suggest encapsulation of the filler with a surfactant to improve the dispersibility of the filler in the biodegradable resin. See page 4, lines 5-9, page 5, lines 37-48 and page 8, line 36 through page 9, line 57.

Frechtling et al discloses the process of coating filler material with polymeric substrates. See col. 2, lines 48-69.

Mollison et al discloses a medical device comprising a supporting structure having a coating on the surface thereof, the coating containing a therapeutic substance, such as, for example, a drug. The purpose of the coating is to serve as a controlled release

vehicle for the therapeutic agent. The coating can be polymeric and can further be hydrophilic, hydrophobic, biodegradable, or non-biodegradable. The material for the polymeric coating can be selected from the group consisting of polycarboxylic acids, cellulosic polymers, gelatin, polyvinylpyrrolidone, maleic anhydride polymers, polyamides, polyvinyl alcohols, polyethylene oxides, glycosaminoglycans, polysaccharides, polyesters, polyurethanes, silicones, polyorthoesters, polyanhydrides, polycarbonates, polypropylenes, polylactic acids, polyglycolic acids, polycaprolactones, polyhydroxybutyrate valerates, polyacrylamides, polyethers, and mixtures and copolymers of the foregoing. See col. 4, lines 57-67 and col. 12, lines 24-45.

Mollison is looked to specifically to document that coating materials based upon polycaprolactones, polyhydroxybutyrate valerates exhibit controlled release or biodegradable activity and would be an acceptable coating material for a filler requiring controlled release capabilities.

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to utilize coated filler materials such as taught by Frechtling et al, as the filler material suggested by the European patent. Furthermore, it would have been obvious to utilize a time-released or biodegradable coating for that filler material such as taught by Mollison et al if biodegradable properties for the filer material were desired.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kriellion A. Sanders whose telephone number is 571-272-1122. The examiner can normally be reached on Monday through Thursday 6:30-7:00.

Art Unit: 1714

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kriellion A. Sanders  
Primary Examiner  
Art Unit 1714

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